

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and for the reasons that follow.

At the very onset, Applicants thank Examiners Sutton and Fetterolf for extending the courtesy of an interview at the USPTO. At this interview, Examiner Sutton indicated that deletion of the phrase “nitric oxide releasing polymers” in claims 49 and 51 would obviate the written description requirement. During the interview, the obviousness rejections of the pending claims over the combined teachings of Cafferata, Arnold (A) and Arnold (B) were discussed. Applicants explained that the current invention is drawn to diazeniumdiolate attached to a benzylic carbon atom of a benzyl-containing polymer and is patentable over the teachings of the cited prior art references.

Claims 1, 2 and 13 are cancelled without prejudice. Claims 3, 4, 37, 53 and 54 are independent claims. Support for new claims 53 and 54 can be found throughout the specification and in particular in paragraphs 31, 32 and Scheme 1 of US published application No. 2007/0286840. Applicants amend claims 3-7, 25, 28-29, 31, 37, 40, 45, 48-49 and 52 to correct claim dependency and to overcome the written description rejection by deleting the phrase “nitric oxide releasing polymers.”

***The Specification Provides Written Description Support for the Claimed Invention:***

Claims 49 and 51 are rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Office states that the specification fails to disclose specific “nitric oxide releasing polymers” and claims 49 and 51 fail to recite structural features common to the members of that genus. Applicants respectfully traverse.

Although Applicants do not acquiesce to the propriety of this rejection, in a good faith attempt to further prosecution, Applicants have amended claims 49 and 52 to delete the objected phrase. Thus, the written description rejection is moot and Applicants respectfully request reconsideration and withdrawal of the rejection.

***Non-obviousness of the Claims in view of the cited References:***

I. Claims 1 and 2 are rejected as unpatentable over Cafferata (U.S. Patent Publication No. 2003/0083739) in view of Arnold *et al.*, Nitric Oxide, 2002 (Arnold (A)). The Examiner has acknowledged that Cafferata does not teach or suggest a polymer composition having a carbon bound diazeniumdiolate attached to a phenyl containing polymer. Furthermore, the Examiner believes that Cafferata's disclosure of "NO-releasing compounds which are bound as pendant groups attached to polymers such as polystyrene" reads on the inventive composition. See Office action at page 4. Applicants respectfully traverse. Claims 1 and 2 have been cancelled, thus, their rejection is moot.

Regarding new claims 53 and 54, Cafferata does not teach or suggest a carbon diazeniumdiolate polymer compound. Rather, Cafferata's focus is on a system and a method for treating vascular restenosis that combines two disparate drugs that act synergistically in one delivery system. Contrary to the Examiner's allegation, the cited part of the Cafferata (page 7) pertains to the application of a "therapeutic substance-polymer solution [which] can be applied to a medical device, such as a stent by either spraying the solution....or immersing the medical device in the solution." See Cafferata, paragraph 35 of published application No. 2003/0083739.

In paragraph 37, Cafferata discloses a laundry list of polymers, including polystyrene, in which the therapeutic drug can be dissolved prior to coating the medical device. Cafferata provides no guidance for covalently linking a NO-releasing moiety to a polymer such as polystyrene, to form a carbon-bound diazeniumdiolate as claimed. Arnold (A), cited to teach a carbon-bound diazeniumdiolate does not remedy these defects of Cafferata. Arnold (A) teaches a phenylene bis-1,4-diazeniumdiolate in which the two diazeniumdiolate moieties are attached to independent carbon atoms of a phenyl ring, rather than to a benzylic carbon atom of a benzyl-containing polymer. The disclosed diazeniumdiolate, therefore, is structurally distinct from the diazeniumdiolate polymer of the claimed invention. Furthermore, as acknowledged by the Examiner, Arnold (A) fails to teach a person of ordinary skill how to attach a diazeniumdiolate to a polymer. Thus, even if Arnold (A) and Cafferata were

combined, their combined teachings would fail to allow a person of ordinary skill in the art to arrive at the inventive composition.

Moreover, as stated by Applicants in their previous response filed November 12, 2008, the stated purpose of Arnold (A) is to investigate the kinetics of NO release from compounds such as the disclosed *bis*-diazeniumdiolate (compound 1, on page 104 of the Arnold (A) article), under acidic conditions. In the absence of any teaching or suggestion in either reference for covalently linking a diazeniumdiolate to a polymer, a skilled artisan would not be motivated or have a reasonable expectation of success for building the claimed composition using the combined teachings of Cafferata and Arnold (A).

In view of the above, claims 53 and 54 are not obvious and Applicants respectfully request reconsideration and withdrawal of this rejection.

**II.** Claims 3, 4, 6, 7, 18, 28, 37, 49 and 51 are rejected under 35 USC §103(a), as being unpatentable over Cafferata (U.S. Patent Publication No. 2003/0083739) in view of Arnold *et al.*, Org. Letters, 2002 (Arnold (B)) and further in view of Arnold *et al.*, Nitric Oxide, 2002 (Arnold (A)). Applicants respectfully traverse.

As stated above, independent claims 53 and 54 are not obvious over the combination of Cafferata and Arnold (A). As disclosed below, Arnold (B) does not remedy the deficiencies of these teachings.

Arnold (B) discloses that acetonitrile can be used as a solvent for the preparation of diazeniumdiolates and reacts with NO in the presence of a base to give methane trisdiazeniumdiolate. Importantly, (B) discloses that although the prior art suggested that one could form a *bis*-diazeniumdiolate nitrile by reacting NO with acetonitrile, the prior art provides no data to support the formation of this compound. Rather, the methane trisdiazeniumdiolate is formed (references 3, 4, in (B)). See abstract and Scheme 1.

Arnold (B) also provides no evidence for the formation of a *bis*-diazeniumdiolate nitrile. Instead, the focus of this article is on the formation of methane trisdiazeniumdiolate from acetonitrile. In this regard, Arnold (B) proposes a hypothetical mechanism for the

formation of the trisdiazoniumdiolate. See Scheme 2 of (B). Because this reference is silent and lacks actual data for the formation of a bis-diazoniumdiolate nitrile, it leaves open the possibility that the disclosed trisdiazoniumdiolate compound can be formed by an alternate mechanism that does not require the formation of a bis-diazoniumdiolate nitrile.

Importantly, Arnold (B) provides no guidance for covalently binding the carbon bound diazeniumdiolate to a phenyl ring of polystyrene, as found in Cafferatta. One of ordinary skill in the art, therefore, would not understand Arnold (B) to teach the formation of the claimed compositions. Additionally, as disclosed in (B), the formation of a bis-diazoniumdiolate nitrile is challenging because of the un-wanted reaction of the cyano group with a base to give the corresponding imidate. See reference 4 in (B) for the reaction of benzylnitrile with NO.

Taken together, the above remarks suggest that one of ordinary skill would not arrive at the current invention by combining the teachings of (B) with Cafferata. Furthermore, the combined teachings of (B) and Cafferata would not result in the medical device of claims 49 and 51.

Independent claims 3, 4 and 37 are, therefore, patentable over the combination of Cafferata, Arnold (A) and Arnold (B). The dependent claims incorporate all the limitations of their respective base claims. Therefore, the dependent claims are also patentable for at least the same reasons mentioned above.

Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to the deposit account.

Respectfully submitted,

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